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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,211	01/30/2002	Klaus Schumann	3868-0103P	9968

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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 05/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,211

Applicant(s)

SCHUMANN ET AL.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10. 6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' letter, filed 03/28/2002; preliminary amendment, filed 01/30/2002; and IDS, filed 7/25/2002.

Claims 1-5 are pending and included in the prosecution.

1. The references cited in the Search Report were not provided on a separate list, however, the references have been considered and are listed on the attached PTO-892 in order to have the references printed on any patent resulting from this application.

Specification

2. The disclosure is objected to because of the following informalities: in page 2, third paragraph, applicants refers to the introductory part of claim 1. Since claims are subject of amendment, referral o the text of the specification would avoid any ambiguity during the course of prosecution.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and ambiguous because it recites that "the substrate sections have been rendered pressure sensitive adhesive", and later the claim recites "the pressure sensitive adhesive surface"; it is not clear to the examiner if all the surfaces of all the substrate sections are rendered pressure sensitive adhesive or only one surface of one of the sections of the substrate is rendered pressure sensitive adhesive.

Clarification is requested.

Claims 2-4 recite the limitation "substrate section", single substrate section, in claim 1. There is insufficient antecedent basis for this limitation in claim 1 because the claim recites "substrate sections", plurality of substrate sections. Furthermore, it is not clear which one of the substrate sections of claim 1 that applicants are referring to.

Claim 5 recites the limitation "the pressure sensitive adhesive substrate sections" in the forth line of claim 5. There is insufficient antecedent basis for this limitation in the claim.

For purpose of examination, and in view of specification, the claims are interpreted as follows:

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Claim 1 reads as a substrate sections or patch sealed in a bag and comprising active substance. One of the surfaces of the substrate sections (it can be the backing layer or the layer containing the active substance) covered by pressure sensitive adhesive layer, and the substrate is provided by a carrier layer (protective layer or release liner) comprises two overlapping sections and larger than the substrate. Claims 2-4 recite the characters of the carrier layer: one section is wider than the other (claim 2); both carrier layer sections are wider than half the width dimension of an undivided carrier layer by the amount of half the overlap (claim 3); and the region of the overlap is positioned centrally or eccentrically (claim 4). Claim 5 reads as a method for forming substrate sections (patch) comprising carrier layer larger than the substrate sections and comprises two overlapping sections; the method comprising dispensing the patch to the carrier layer sections after the later have been overlapped.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/34633 ('633) in view of US 5,626,866 ('866).

WO '633 teaches a dressing set (substrate sections) that keeps the active agent in a reservoir at a constant level for a prolonged storage time (abstract; page 2, last paragraph). The dressing set comprising a backing; a reservoir containing at least one pharmaceutically active substance; a pressure sensitive adhesive surface layer on one of the surfaces of the backing layer (reads on one of the surfaces of the substrate sections rendered pressure sensitive adhesive); and more than one peel stripes, i.e. the carrier sections (abstract). The peel stripes extend beyond the edges of the dressing and are overlapping (page 4, paragraph 3, figure 2). It is evident from figure 2 that both carrier layer sections are overlapping in the center of the dressing (claim 4). Figure 2 also shows that one carrier section is wider than the other by the amount of the overlap (claim 2). It is also expected that if we have a carrier layer and divide it into two pieces and partially overlap the two pieces on top of each other, it is expected to have shorter width of the overlapped sections than the undivided carrier. Thus, in order to have the overlapped carrier sections having same width of the undivided carrier layer we have to increase the width by the amount of the overlap and this increase can be added on one

side or divided on both sections of the carrier, and in the later situation it will give half the amount of overlap on each side (claim 3). In any events, applicants are not claiming any dimensions of the carrier layer sections or the overlapping portions that impart patentability to the claims.

However, WO '633 does not teach that the substrate sections are sealed in a bag.

US '866 teaches a transdermal drug delivery device or patch to deliver volatile drugs comprising a drug-containing adhesive layer or reservoir and a peelable release liner (abstract; col.1, lines 10-12; col.3, lines 48-49; col.8, lines 35-37). The release liner formed of two stripes that overlap in the center (col.12, lines 17-23; figure 4). The patch is sealed in a pouch (col.12, lines 32-33). The adhesive used in the device is a pressure sensitive adhesive (col.8, lines 30-37).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of WO '633 that teaches dressing or patch comprising active agent and release liner comprising two overlapping sections with the teachings of US '866 that sealed the patch containing volatile drugs in a bag or pouch, to obtain a patch with overlapped release liner-sections sealed in a bag, motivated by the desire of WO '633 to keep the active agent in the reservoir at a constant level for a prolonged storage time, or motivated by the desire of US '866 to protect volatile drugs during storage (as also desired by applicants), with reasonable

expectation to achieve increased stability of the drugs in the patch and prevent their leak from the reservoir layer during storage of the patch in a sealed bag.

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,174,399 ('399).

US '399 teaches a method of producing an adhesive bandages comprising a backing layer, on its center deposited a pad (represents the substrate section) and covered by overlapping release layers (carrier sections) that extends beyond the pad (col.2, lines 10-15; col.3, lines 40-43; figure 1). The process of making the adhesive bandage comprises the steps of laminating the adhesive bandages then applying the release layers that fed from two rolls and overlap in the center of the pad (col.3, lines 38-42; Figure 1).

The reference differs from the present invention in that it does not teach the carrier layer sections (release liners) are applied after the sections have been overlapped. However, the reference teaches, as also evident from Figure 1, that both sections of the liner are overlapped during the process of their application because they are fed from two rolls.

The process comprising the step of overlapping the release liner before application of the substrate does not impart patentable distinction to the process of the prior art that overlapped the two portions during their application, nor resulted in a materially different product, absent evident to the contrary. Selection of any order of

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performing process steps is *prima facie* obvious in absence of new or unexpected results, see *In re Burham*, 154 F.2d 690 USPQ 330 (CCPA 1946); and *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to produce a substrate sections (patch) comprising a carrier layer sections that extend beyond the substrate sections and form a region of overlap, said process comprising the step of overlapping the carrier layer sections before or during application to the substrate sections because the change of sequence of the step is within the skill in the art as it does not materially affect the end product, with reasonable expectation of the delivered substrate as a stable drug delivery device or wound dressing.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
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Isis Ghali